New Therapy for Heart Attack Patients Approved by FDA for Clinical Trials

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San Francisco, CA – A new approach using stem cells to repair the damage caused by heart attacks has been given approval for first-in-human use in clinical trials by the Food and Drug Administration.

Funding for research that contributed to the potential therapy came from California's stem cell agency, the California Institute for Regenerative Medicine (CIRM), through a Disease Team grant to Cedars-Sinai Heart Institute in Los Angeles.

"This is the first time that research by a CIRM-funded Disease Team has resulted in an Investigational New Drug (IND) approval from the FDA, a critical step in testing promising therapies in patients," says Ellen Feigal, MD, Senior Vice President for Research and Development at the stem cell agency. "It's a reflection of the initial progress being made in advancing scientific discoveries towards potential therapies for patients."

The therapy, which will be taken forward by Los Angeles-based biotechnology company Capricor, uses Cardiosphere Derived Cells (CDCs) to reduce scarring and repair the damage caused to heart muscle by a heart attack. The cells are found in heart tissue and have the potential to change into a variety of different heart cell types. The CIRM funded work enabled development of an "off the shelf" product that has the potential to treat large numbers of patients and be available whenever a patient needs it. The theory is that these cells will help support the heart's own healing mechanisms.

In preliminary studies with a related product derived from the patient's own cells (e.g., not an "off the shelf" product), giving patients these modified CDCs were shown by an imaging study to reduce the amount of scarring left by the heart attack.

Eduardo Marban, MD, PhD, Director of the Cedars-Sinai Heart Institute, led the research into the therapy. His work was supported by the $5.5 million Disease Team Award to Cedars-Sinai from the California stem cell agency, which was created by the voter-approved Proposition 71.

Dr. Marbán said, "By funding our preclinical studies on adult stem cells from the heart, CIRM has shown its commitment to developing practical, here-and-now treatments. In the next phase of clinical testing we hope to achieve the shared goal of making regenerative medicine a reality for the millions of patients afflicted by 'irreversible' heart disease."

The Disease Team Awards fund research that includes basic scientists and clinicians from both academia and industry. The goal is to create collaborations that will speed up the process of moving promising therapies from the lab into clinical trials by insuring that clinically relevant issues are considered early and avoiding potential safety issues being discovered late in the process

"Every year in the US around one million people have a heart attack," says Robert Quint, MD, a patient advocate for heart disease who serves on the CIRM governing board. "Those who survive often have life-long complications as a result of the attack. Dr. Marban's research using cardiac derived stem cells has vastly improved the initial results using bone marrow and other sources. I believe that this will potentially improve the lives of many heart attack victims throughout the world in the not too distant future. It is a substantial leap forward."

A description of Dr. Marban's Disease Team Award can be found on our website.

About CIRM: CIRM was established in November 2004 with the passage of Proposition 71, the California Stem Cell Research and Cures Act. The statewide ballot measure, which provided $3 billion in funding for stem cell research at California universities and research institutions, was overwhelmingly approved by voters, and called for the establishment of an entity to make grants and provide loans for stem cell research, research facilities, and other vital research opportunities. A list of grants and loans awarded to date may be seen here: http://www.cirm.ca.gov/for-researchers/researchfunding.

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